



## Complete Summary

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### **GUIDELINE TITLE**

Bacterial vaginosis.

### **BIBLIOGRAPHIC SOURCE(S)**

New York State Department of Health. Bacterial vaginosis (BV). New York (NY): New York State Department of Health; 2009 Aug. 7 p. [22 references]

### **GUIDELINE STATUS**

This is the current release of the guideline.

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## SCOPE

### **DISEASE/CONDITION(S)**

- Human immunodeficiency virus (HIV) infection
- Bacterial vaginosis (BV)

### **GUIDELINE CATEGORY**

Counseling  
Diagnosis  
Evaluation  
Management  
Screening  
Treatment

### **CLINICAL SPECIALTY**

Allergy and Immunology  
Family Practice  
Infectious Diseases  
Internal Medicine  
Obstetrics and Gynecology

## **INTENDED USERS**

Advanced Practice Nurses  
Health Care Providers  
Nurses  
Physician Assistants  
Physicians  
Public Health Departments

## **GUIDELINE OBJECTIVE(S)**

To provide guidelines for diagnosis and management of bacterial vaginosis (BV) in human immunodeficiency virus (HIV)-infected patients

## **TARGET POPULATION**

Human immunodeficiency virus (HIV)-infected patients with bacterial vaginosis (BV)

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Diagnosis/Evaluation**

1. Obtaining a history of vulvar and vaginal symptoms
2. Diagnosis using Amsel's criteria

### **Management/Treatment**

1. Treatment of non-pregnant women: metronidazole (oral or gel) or clindamycin cream; alternative regimen: oral clindamycin or clindamycin ovules
2. No treatment for asymptomatic bacterial vaginosis (BV)
3. Management of pregnant women:
  - Screening all pregnant women for BV
  - Treatment with oral metronidazole or clindamycin
4. Management of partners
  - Patient education
  - Quantitative ribonucleic acid polymerase chain reaction (RNA PCR) and consultation with an experienced human immunodeficiency virus (HIV) provider
  - HIV antibody testing
  - Assistance with partner notification

## **MAJOR OUTCOMES CONSIDERED**

- Complications of pregnancy
- Adverse outcomes of pregnancy

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
 Hand-searches of Published Literature (Secondary Sources)  
 Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)  
 Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

#### Quality of Evidence for Recommendation

- I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
- II. One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes
- III. Expert opinion

### METHODS USED TO ANALYZE THE EVIDENCE

Review  
 Review of Published Meta-Analyses

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency virus (HIV) infection. Committees\* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees\* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

\*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physician's Prevention Advisory Committee
- Pharmacy Advisory Committee

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Strength of Recommendation**

- A. Strong recommendation for the statement
- B. Moderate recommendation for the statement
- C. Optional recommendation

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Definitions for the quality of the evidence (I, II, III) and strength of recommendation (A-C) are provided at the end of the "Major Recommendations" field.

#### Diagnosis

A history of vulvar and vaginal symptoms should be obtained on all women presenting for care including: **(AIII)**

- Changes in vaginal discharge/vaginal malodor
- Vulvovaginal irritation, pruritus, burning, swelling
- Dyspareunia, dysuria

Amsel's criteria should be used to diagnose bacterial vaginosis (BV). Positive diagnosis requires the presence of three of the following four criteria: **(AII)**

1. Homogeneous thin white discharge coating the vaginal walls
2. Clue cells present on microscopy of vaginal saline preparation
3. Vaginal fluid pH >4.5
4. Positive whiff test (fishy odor of vaginal discharge with or without the addition of 10% potassium hydroxide [KOH])

#### Treatment of Bacterial Vaginosis in Non-Pregnant Women

HIV-infected women with symptomatic bacterial vaginosis who are not pregnant should be treated with the metronidazole or clindamycin regimens specified in Table 1 of the original guideline document. **(AI)**

Human immunodeficiency virus (HIV)-infected women with asymptomatic bacterial vaginosis should not be treated. **(AI)**

#### Treatment of Bacterial Vaginosis in Pregnant Women

Clinicians should:

- Screen all HIV-infected pregnant women for bacterial vaginosis at their first prenatal visit **(AII)**
- Treat all HIV-infected pregnant women with symptomatic bacterial vaginosis **(AI)**
- Treat HIV-infected pregnant women who have asymptomatic bacterial vaginosis and a history of preterm labor **(AIII)**

Clindamycin cream should not be used to treat bacterial vaginosis in HIV-infected pregnant women; instead, either oral metronidazole or clindamycin should be used (see Table 2 in the original guideline document). **(AI)**

## Management of Partners

### Management of HIV Exposure in Partners

When HIV-infected patients present with a new sexually transmitted infection (STI), clinicians should encourage their partner(s) to undergo HIV testing at baseline, 1, 3, and 6 months. **(AIII)** In New York State, HIV diagnoses must be confirmed by a Western blot assay.

Clinicians should educate patients to be vigilant for any post-exposure acute HIV symptoms in their partners, such as febrile illness accompanied by rash, lymphadenopathy, myalgias, and/or sore throat. **(AIII)** If the partner presents with signs or symptoms of acute HIV seroconversion, a quantitative ribonucleic acid polymerase chain reaction (RNA PCR) should be obtained, and consultation with an HIV Specialist should be sought. **(AIII)** Positive RNA tests should be confirmed with HIV antibody testing performed within 6 weeks of the RNA test.

Clinicians should offer assistance with partner notification if needed, or refer patient to other sources for partner notification assistance (Contact Notification Assistance Program [CNAP], PartNer Assistance Program [PNAP]). **(AIII)**

### Definitions:

### Quality of Evidence for Recommendation

- I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
- II. One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes
- III. Expert opinion

### Strength of Recommendation

- A. Strong recommendation for the statement
- B. Moderate recommendation for the statement
- C. Optional recommendation

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate diagnosis and management of bacterial vaginosis (BV)

### **POTENTIAL HARMS**

Not stated

## **CONTRAINDICATIONS**

### **CONTRAINDICATIONS**

Clindamycin cream should not be used in human immunodeficiency virus (HIV)-infected pregnant women because it has been associated with adverse events such as low birthweight and neonatal infection if used during the second half of pregnancy.

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

## **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the Clinical Education Initiative (CEI) and the AIDS Education and Training Centers (AETC). The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Getting Better  
Living with Illness

### **IOM DOMAIN**

Effectiveness  
Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

### **BIBLIOGRAPHIC SOURCE(S)**

New York State Department of Health. Bacterial vaginosis (BV). New York (NY): New York State Department of Health; 2009 Aug. 7 p. [22 references]

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2009 Aug

### **GUIDELINE DEVELOPER(S)**

New York State Department of Health - State/Local Government Agency [U.S.]



## **SOURCE(S) OF FUNDING**

New York State Department of Health

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI Institute on April 19, 2010.

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